

## **Remarks**

Applicant respectfully acknowledges that the objection under 35 U.S.C. § 132(a) and the rejection under 35 U.S.C. § 112, second paragraph, have been withdrawn.

### **A. Claim Amendments**

Claim 23 has been amended to include the limitation that the transfer factor is purified. This limitation is supported in at least paragraphs 21, 48, and 62 of the specification. Thus, the amendment does not introduce new matter into the application. New claims 32 and 33 have been added to the application. Claim 32 requires that after recovering the transfer factor-containing fluid, an amount of raw egg yolk is added to the transfer factor-containing fluid. This amendment is supported in at least paragraphs 22 and 51 of the application and does not introduce new matter. Claim 33 requires that the egg which is collected from the immunized hen is fertilized. This amendment is supported in at least paragraph 42 of the application and does not introduce new matter.

### **B. Rejection Under 35 U.S.C. § 102(b)**

The Examiner rejected Claims 23, 26 – 28, and 31 under 35 U.S.C. § 102(b) as anticipated by Tokoro. Applicant respectfully asserts that the amended claims of the present application are not anticipated by Tokoro. Specifically, the claims of the present application are not anticipated by Tokoro because Tokoro does not teach the production of a transfer factor.

### **Claims 23, 26 – 28, and 31**

Claim 23 of the application has been amended to require that the transfer factor is purified. In contrast, Tokoro teaches the use of a 0.45 µm filter. A 0.45 µm filter

would not be useful for separating any transfer factor that was present therein from larger molecules, such as antibodies, because antibodies, viruses, mycobacteria, and even some bacteria that are much larger than 10,000 Da will pass through 0.45  $\mu$ m pores. Thus, the final composition in Tokoro is not purified, as required by the present claims.

In addition, despite the fact that transfer factors have been studied for over 50 years and over 3,000 articles have been published in peer-reviewed scientific journals regarding transfer factors, Tokoro lacks any discussion of transfer factors. Tokoro does not teach that transfer factor is present in its hen eggs but, rather, that a “transfer factor-like component” is present in the eggs. By using the term “like” in the description of the “transfer factor-like component”, Tokoro teaches that something other than transfer factor was actually present in the eggs and, thus, Tokoro cannot anticipate the present invention.

“Transfer factor-like” is a term of art that indicates a substance which has transfer factor-like activity, but is not actually transfer factor. The term “transfer factor-like” is described in Dunnick, W., *et al.*, “*Lack of Antigen Fragments in Guinea Pig Transfer Factor-like Activity*,” Clin. Immunol. and Immunopathol. 17:55-65 (1980) (copy enclosed). Dunnick refers to the substance evaluated therein, which has transfer factor-like activity, as “TFLA”. Based on the experiments described in the reference, Dunnick concludes that superantigenicity, a characteristic of transfer factor (p. 55), “cannot explain the activity of TFLA.” (Dunnick, p. 65). Dunnick states that “[w]hereas transfer factor and TFLA are structurally similar . . . and the tests for the two are related, no direct relationship has been established between TFLA and *in vivo* transfers of

cellular immunity.” (Dunnick, pg. 65). It has long been known that transfer factors are capable of transferring cellular immunity *in vivo*. Thus, it is clear that transfer factor is different from the “transfer factor-like component” of Tokoro and that a “transfer factor-like component” will not necessarily transfer immunity. Therefore, Tokoro cannot anticipate the present invention.

In its disclosure, Tokoro even suggests that its “transfer factor-like component” is not actually transfer factor. The Tokoro reference states, “the immunological functions of the transfer factor-like component . . . are not known.” (Tokoro, col. 7, lines 44-47). In contrast, the immunological functions of transfer factor are and have been known for years. Additionally, Tokoro states that “[t]here is a possibility that a part of the transfer factor-like component is the same as the food factor described in [U.S. Pat. No. 4,402,938].” (Tokoro, col. 7, lines 51-54). If, as Tokoro asserts, there is a possibility that its transfer factor-like component is the same as the food factor described in U.S. Pat. No. 4,402,938, it cannot also be transfer factor. This statement is further evidence that even Tokoro does not believe that its “transfer factor-like component” is truly transfer factor. If Tokoro believed its “transfer factor-like component” were transfer factor, the reference would reflect this.

MPEP § 2131 provides that a claim is anticipated only if each and every element as set forth in the claim is described in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in complete detail as contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Because Tokoro does not teach every element of the claim, namely

the production of transfer factor, it cannot anticipate the present invention and a *prima facie* case of anticipation has not been satisfied.

The Examiner asserts that “the name used to describe the crude preparation obtained by the method of Tokoro is irrelevant because it contains all molecules less than 10,000 mw, including transfer factor.” Merely because the emulsion is filtered to contain “all molecules less than 10,000 mw” and a “transfer factor-like component” was recovered from that emulsion, and transfer factor has a molecular weight of less than 10,000, does not mean that the “transfer factor-like component” is transfer factor. For example, both ethanol and water have a molecular weight that is less than 50. Ethanol and water are not the same substance merely because they both have molecular weights of less than 50. Similarly, the method of Tokoro does not necessarily result in a product that contains transfer factor merely because Tokoro uses a filtration step that separates particles having a molecular weight of less than 10,000. As discussed above, the term “transfer factor-like component” has a specific meaning in the art and it is clear that Tokoro does not believe its “transfer factor-like component” is transfer factor. Accordingly, a *prima facie* case of anticipation has not been satisfied.

### **New Claim 32**

New claim 32 of the application requires that after recovering the transfer factor-containing fluid, an amount of raw egg yolk is added to the transfer factor-containing fluid. The inventors believe that egg yolks, in their natural, raw, untreated state, help preserve the bioactivity of the transfer factor when it passes through the digestive tract. The addition of raw egg yolk to the composition may be particularly helpful as the transfer factor transits through the acidic conditions of the stomach. The

supplementation of the raw egg yolk to the transfer factor-containing fluid results in higher bioactivity and actual quantities of effective transfer factor in the gut and lower digestive tract. See paragraphs 22 and 51 of the application.

Tokoro does not teach or suggest that any raw, untreated egg yolk should be added to the final composition. Because Tokoro fails to teach or suggest this aspect of the claim, Applicant believes that Claim 32 is novel over Tokoro.

### **New Claim 33**

Claim 33 requires that the egg which is collected from the immunized hen is fertilized. The inventors believe that fertilized eggs may contain more transfer factor than otherwise comparable non-fertilized eggs. Fertilization and the resultant growth of the embryo may stimulate the production of transfer factor due to the onset of mitosis and related cellular processes. See paragraph 42 of the application.

Tokoro does not teach that the egg from which the transfer factor is collected should be fertilized. Because this aspect of the claim is not taught, Tokoro cannot anticipate claim 33 of the application.

### **C. Rejection Under 35 U.S.C. § 103(a)**

The Examiner rejected Claims 23 and 26 – 31 under 35 U.S.C. § 103(a) as obvious over Tokoro in view of Anderson. The above arguments apply equally to the obviousness rejection and should be deemed to be repeated here. The combination of references fails to teach or suggest all elements of the claims. MPEP § 2142 - § 2143 requires that in order to make a *prima facie* case of obviousness, the cited prior art reference must teach or suggest all the claim limitations. Anderson is wholly unrelated to transfer factors. As discussed above, Tokoro fails to teach the production of a

transfer factor. Because the combination of Tokoro and Anderson do not teach or suggest a "process for producing transfer factor," the references cannot satisfy a *prima facie* case of obviousness.

In addition, Tokoro teaches away from the claims of the present invention by teaching that, unlike transfer factor, its "transfer factor-like component" has unknown immunological properties. Tokoro also asserts that, unlike transfer factor, part of the "transfer factor-like component" may be the same as a food factor. Teaching away is the antithesis of art suggesting that the person of ordinary skill go in the claimed direction. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Thus, it is clear that upon reading Tokoro, one skilled in the art would not be led to use the method of present invention to produce transfer factor. Accordingly, the Examiner has not satisfied a *prima facie* case of obviousness in this case.

In summary, Applicant submits that the claims and specification are now in condition for allowance. It is respectfully submitted that claims 23-31 are patentably distinct over the references cited by the Examiner and meet all other statutory requirements. Therefore, reconsideration of the rejections in the Office Action is respectfully requested. The Examiner is invited to telephone the undersigned should any issues remain after the consideration of this response.

Please charge any additional fees that may be required to Deposit Account No. 50-2548.



Respectfully requested,

NELSON MULLINS RILEY & SCARBOROUGH

April 4, 2007  
Date

Nichole Andrighetti  
Nichole Andrighetti  
Registration No. 56,508  
Meridian, Suite 1700  
1320 Main St.  
Columbia, SC 29201  
Phone: (864) 250-2292  
Fax: (803) 255-9831